UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' REPLY BRIEF IN FURTHER SUPPORT OF MOTIONS FOR PARTIAL SUMMARY JUDGMENT

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I. PARTIAL SUMMARY JUDGMENT ON CLAIMS AND FACTS IS PERMISSIBLE AND WILL STREAMLINE THE TRIAL.

Rule 56(g) authorizes the Court to "enter an order stating any material fact—including an item of damages or other relief—that is not genuinely in dispute and treating the fact as established in the case." *Murzuq v. Loury*, No. 09-3933(RBK), 2011 WL 2221180, *4 (D.N.J. June 6, 2011)(Kugler, J.) This mechanism should be utilized to streamline the trial, to the extent partial summary judgment is not entered.

Defendants focus on a single unpublished decision that questions the legitimacy of Rule 56's unequivocal language permitting partial summary judgment for both claims and facts, based on their hope that the Court will find that any fact question they dream up will defeat the motion even if not supported or material. (Defs.' Br. 4-5). To be clear, *Evans v. Nat'l Auto Div., L.L.C.* relies entirely on cases predating the 2010 amendment to Rule 56, which amended "[t]he first sentence … to make clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim, defense, or part of a claim or defense" and added Section (g) to the Rule. Advisory Comm. Notes 2010 Amend. And the Court in *Evans* observed, "[I]t simply doesn't appear that resolution of the present motion would materially advance the litigation in any way." 2016 WL 4770033, at *4.

In contrast, Plaintiffs' motions would significantly streamline the trial of this case. For example, as things stand now, Plaintiffs and Defendants will need to call

or play videos of numerous fact and expert witnesses as to the subject matter of the motions, including for example that the required regulatory representations by the Defendants constituted binding warranties that were violated; NDMA and NDEA are genotoxic, probable human carcinogens; cGMP's were violated; the statutory definition of adulteration is met; and the contamination precluded the sale of the API and VCDs. Resolution of these and the other issues will streamline the trial and focus the jury on the only true question, the amount of damages.

II. THE VALSARTAN API AND VCDS WERE ADULTERATED.

The FDA determined that the ZHP valsartan API at issue in this trial was adulterated based on the extensive cGMP violations in the development and manufacture of the contaminated drug product, and this resulted in the import ban. (Pls.' Affirm. ZHP SOMF ¶ 43-54)). Defendants wish to downplay the significance of the November 29, 2018 Warning Letter, but the FDA is clear that such letters are only issued based on a finding of "**significant violations**":

> The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. A Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act).

(FDA, Reg. Proc. Man. § 4-1-1, at 4, https://www.fda.gov/media/71878/download). Here, the FDA found that the Defendants' VCDs were "adulterated" due to significant CGMP violations. In addition, Teva and Torrent's finished dose VCDs

were adulterated because they incorporated ZHP's API. (Torrent SOMF ¶¶ 17, 48 (FDA also advised Torrent that its FD was adulterated); (Teva SOMF ¶¶ 8-23); *see also* 21 U.S.C. § 321(g)(1)(D), 351). Moreover, the FDA did impose an enforcement action on ZHP by placing it on its most severe import alert.[1] (Pls.' Affirm. ZHP SOMF ¶ 46).

Moreover, Defendants make no rational argument to avoid the fact that the contamination rendered the quality and purity of the drug product non-compliant with the compendial specifications, and thus not therapeutically equivalent. (*Id.* at 52, 135-144; Pls. Opp. to Defs.' SOMF ¶ 76). Both of these undisputable facts satisfy the statutory definition of adulteration. There is no real argument to the contrary.

Defendants rely on the Court's observation in the *Daubert* rulings that a fact question is presented. But Defendants lose sight of the differing procedural posture—this motion is the time for the Court to rule on the issue as a matter of law. Since the facts are completely one-sided, and no juror could reasonably find to the contrary, summary judgment is appropriate. The adulteration of the API and VCDs containing the contaminated API should be determined because there is no genuine issue of material fact. This determination by the Court will significantly streamline and focus the trial.

[1] FDA "Actions & Enforcement" webpage listing import alerts as one of the enforcement actions that can be taken. (https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/actions-enforcement).

III. DEFENDANTS EXPRESSLY WARRANTED THAT THEIR VCDS WERE FDA APPROVED AND USP AND CGMP COMPLIANT.

Defendants apparently believe selling prescription medicines contaminated with genotoxic probable human carcinogens is acceptable, and mischaracterize their express warranties as "unsubstantiated assertions." (Defs.' Br. 8). To be clear, Defendants expressly warranted that their API and VCDs were "valsartan" as approved by the FDA. For example, the ZHP Defendants represented to their API customers that the valsartan API was compliant with the US DMF—which affirmatively represented that there were no genotoxic nitrosamines in the drugs, and that warranty flowed all the way downstream. (Pls.' Affirmative SOMF ¶ 126-134; 145-154.5). And the labels state that the VCDs were manufactured by ZHP and were USP compliant:

(PRINSTON00035230 (ZHP Ex. 97); *see also* Pls.' Br. 7). Part of being FDA approved and USP compliant is complying with cGMPs. 21 U.S.C. 314.105(a); U.S.C. 314.125(13); (Pls.' Affirm. ZHP SOMF ¶ 52; Pls.' Opp. to Defs.' SOMF ¶ 76). All FDA approved drugs are listed in the Orange Book as AB-rated and

therapeutically equivalent to their RLDs. (*Id.* at ¶ 147 *see also* 21 C.F.R. § 314.3). Thus, a representation that a drug is FDA approved is the gateway to and also warrants that it is in the Orange Book. The truth was the opposite: the contamination presented "an unacceptable carcinogenic risk to the intended patient population." (Pls.' Affirm. ZHP SOMF ¶ 143 (quoting the ZHP Defendants)).

Defendants' reliance on SummaCare's testimony that it "had no 'warranties in place' with" Defendants and Emblem's testimony that "it was not aware of any express warranties," is of no moment. (Defs.' Br. 9-10). First, the questions asked were narrow and limited in pursuit of catchy but uneventful sound bites. The key representations relied on by the TPPs were ignored in the questioning. (Pls. Opp. to Defs' SOMF ¶ 84-85, 108, 119; MSP Ex. 17 (the TPPs were [redacted] Liability here does not rest on Summacare's, Emblem's, or any other class members' "hav[ing] to 'perceive' the package labelling or insert," because the representations at issue (FDA approval, Orange Book AB rated, USP and cGMP compliance) are required in order to permit the sale of the VCDs at every

step of the stream of economic transactions at issue. *In re Valsartan, Losartan, Irbesartan Prods. Liab. Litig.*, MDL No. 2875 (RBK-JS), 2021 WL 222776, at *11 (D.N.J. Jan. 22, 2021) (ECF 775); (Pls.' Opp. to Defs,' SOMF ¶ 83-86, 88, 92-93); *Mylan Labs Ltd. v. U.S. Food & Drug Admin.*, 910 F. Supp. 2d 299, 301 (D.D.C. 2012); *U.S. v. Lanpar Co.*, 293 F.Supp. 147, 153-54 (N.D. Tx. 1968).

Defendants add the absurd argument that their warranties of FDA approval and USP and cGMP compliance may not carry the legal meaning that they do. (Defs.' Br. 11). FDA approval, AB rating, and USP and cGMP compliance carry explicit legal significance in the highly regulated pharmaceutical industry. Defendants do not offer any reasonable contrary interpretation.

IV. THE FDA'S WARNING LETTER, ITS IMPORT BAN, AND DEFENDANTS' OWN ADMISSIONS DEFINITIVELY PROVE THAT DEFENDANTS' VCDS WERE ADULTERATED.

Defendants desperately gloss over the FDA's November 29, 2018 Warning Letter finding the valsartan to be adulterated, describing it as "not a definitive finding by the FDA." (Defs.' Br. 2). They cite a series of inapposite cases in support of this argument. The first case—*Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 943-45 (D.C. Cir. 2012)—rejected the plaintiff's claim under the APA against the FDA for issuing a warning letter, observing that, "[a] Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug and Cosmetic Act." *Id.* at 944 (quoting FDA Manual,

§ 4–1–1). Defendants then cite a series of cases for the uncontroversial observation that warning letters do not support claims related to issues not mentioned in the warning letters.[2] That is not an issue here. (Pls.' Affirm. ZHP SOMF ¶ 47-51).

Defendants also completely ignore the fact that the FDA placed ZHP on import alert for the violations listed in the Warning Letter, and all Defendants recalled their VCDs for the same reason, despite initially trying to avoid such a recall. (Pls.' Affirm. ZHP SOMF ¶ 46, 143; Pls.' Opp. to Defs.' SOMF ¶ 2). Moreover, Defendants' witnesses admitted to numerous compendial and cGMP violations related to the NDMA/NDEA contamination. (Pls.' Br. 12-22).

Defendants ask this Court not to exercise its authority to find that no triable factual dispute exists under Rule 56. (Defs.' Br. 12-13). Here, the only reasonable

[2] *Gross v. Stryker Corp.*, 858 F.Supp.2d 466, 493, 497 (W.D. Pa. 2012) (quoting cGMP violations untethered to the defect alleged by the plaintiff); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) ("Plaintiff has failed to demonstrate that the injuries she sustained resulted from the federal violations spelled out in the warning letters"); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (same); *Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 228 (W.D.N.Y. 2016) ("Plaintiff here has not alleged any facts connecting the 2013 Warning Letter to his case"); *Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203(JS)(WDW), 2014 WL 2863087, at *5 (E.D.N.Y. June 23, 2014); *Alra Lab'ys, Inc. v. Am. Cyanamid Co.*, No. 92 C 2252, 1996 WL 377070, at *4-5 (N.D. Ill. July 2, 1996) ("As far as we can tell, the FDA reports did not cite any violations which directly affected Eryzole sold to Cyanamid," **but rejecting the argument that the court had "no jurisdiction to decide the factual question of whether Cyanamid's Eryzole was adulterated"**). Defendants also cite *Healthpoint, Ltd. v. Stratus Pharm.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001), which concerned the plaintiff's request for "preliminary injunctive relief," in a very different factual context.

finding is that Defendants' VCDs were adulterated. No reasonable juror could find otherwise in the face of the evidence including the FDA's Warning Letter, the import alert, the recalls, and Defendants' own admissions to compendial and cGMP violations, all due to or causing the NDMA/NDEA contamination.[3] *See In re Enter. Rent-A-Car Wage & Hour Emp. Pracs. Litig.*, 683 F.3d 462, 471 (3d Cir. 2012) (affirming summary judgment because the "evidence in the instant case so favors the defendant that we conclude no reasonable juror could find that Enterprise Holdings, Inc. was the plaintiffs' employer"); *El v. Southeastern Pa. Transp. Auth. (SEPTA)*, 479 F.3d 232, 248 (3d Cir. 2007) (affirming summary judgment because "[t]aking all of the record evidence into account, there is no substantive evidence on which a reasonable juror could find that SEPTA's policy is inconsistent with business necessity").

V. DEFENDANTS' CONTAMINATED VCDS DID NOT COMPLY WITH THEIR FDA APPROVALS AND ORANGE BOOK LISTING.

Defendants seek to prove their VCDs complied with their FDA approvals without even referencing those approvals, none of which indicated that their VCDs were contaminated with NDMA and NDEA. (Defs.' Br. 17; Pls. Affirm. ZHP SOMF ¶ 126-134; Teva SOMF ¶ 38-39, 41; Torrent SOMF ¶ 35-37). **ZHP's DMFs explicitly and falsely stated, "there was not any high potency genotoxic group,**

[3] Plaintiffs discuss Defendants' misrepresentations of the FDA's press releases in their Opposition to Defendants' SOMF Paragraphs 61-65, 81-82.

such as N-nitroso compounds" in its valsartan made with both processes at issue. (Pls. Opp. to Defs.' SOMF ¶ 83, 88). Defendants run away from their wrongdoing and point to two irrelevant regulatory concepts that Plaintiffs do not rely on in support of their claims.[4] (Defs.' Br. 17). This is typical of Defendants' look-here-not-there strategy, and the Court should not allow this to reach a jury.

VI. THE USP DID NOT PERMIT DEFENDANTS TO CONTAMINATE THEIR VCDS WITH GENOTOXIC PROBABLE HUMAN CARCINOGENS.

Defendants peddle the illogical argument that "[w]ith respect to USP specifications, Plaintiffs are conflating the lack of any specific limit for NDMA and NDEA in the USP monograph for valsartan API with a prohibition on its presence." (Defs.' Br. 25). Any suggestion that the lack of reference to NDMA and NDEA in the USP permitted their presence in the drugs should be rejected out of hand. And Defendants ignore the USP requirements to identify genotoxic probable human

[4] To be clear, Plaintiffs' opening brief focused on Defendants' VCDs failing to be therapeutically equivalent to their RLDs, as stated in the Orange Book due to their FDA approval. (Pls.' Br. 7-8, 19-21, 26, 29, 34). Plaintiffs' opening brief mentions "pharmaceutical equivalents" and "bioequivalence" in one block quote defining therapeutic equivalence. (*Id.* at 20-21). Plaintiffs rely on Defendants' failure to ensure their VCDs (1) "meet compendial or other applicable standards of strength, quality, purity, and identity," (2) "are adequately labeled," (3) "are manufactured in compliance with Current Good Manufacturing Practice regulations," to establish Defendants' VCDs were not therapeutically equivalent to their RLDs. (Pls.' Br. 20-21). Crucially, the approved forms of the relevant RLDs (Diovan and Exforge) did not include NDMA or NDEA impurities in any regulatory or compendial document describing the approved formulation of those drugs. (Pls.' Affirm. ZHP SOMF ¶ 10).

carcinogens, like NDMA and NDEA, and then test for and report those contaminants, when they changed their manufacturing processes (and introduced these contaminants in the first place). (Pls. Opp. to Defs.' SOMF ¶ 76). Importantly, the USP prohibits toxic substances, such as the genotoxic probable human carcinogens NDMA and NDEA,[5] from being listed under the other impurities section. (*Id.*). This explicitly refutes Defendants' inaccurate claim that "the USP prescribed a .1% threshold for variance with branded valsartan, a limit Plaintiffs are unable to show the VCDs ever exceeded." (Defs. Opp. Br. 26-27). This argument is absurd. Treating NDMA or NDEA as "any other impurity" at 0.1% (*i.e.,* 1,000 ppm) would mean controlling NDMA and NDEA *in excess of 3,000 times* (for NDMA) and *12,000 times* (for NDEA) the acceptable intake limits of 0.3 and 0.08 ppm established by the FDA. (Defs. Br. 26-27.) Moreover, no threshold applies to NDMA or NDEA by definition. (Pls.' Affirm. ZHP SOMF ¶ 61-62, 86-87). If Defendants were correct, drug manufacturers could secretly contaminate their products with harmful substances as long as they omit the contaminants from their specifications. They cannot.

VII. DEFENDANTS HAVE NO BASIS FOR THEIR UNDERSTANDING OF THE JULY 27, 2017 EMAIL.

Defendants continue to pretend the July 27, 2017 email "is not about Valsartan

[5] There is no dispute that NDMA and NDEA are genotoxins and probable human carcinogens. (Pls. Br. 22-26).

API[,] … is susceptible to varying interpretations[,] and … cannot make up for ample contrary evidence belying the notion that ZHP had any reason to know of the potential for nitrosamine formation." (Defs.' Br. 21-22; ZHP's Opp. Br. 1-8). The email was confirmed by numerous ZHP witnesses and ZHP itself before its new counsel decided to pretend that it does not **correctly** say that the impurity being discussed "**is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite**," among other things. (Pls.' Affirm. ZHP SOMF ¶ 35-42.5). Min Li, speaking for ZHP, confirmed what the email said and his fanciful explanation that Dr. Lin successfully "guessed" that NDMA was present and caused by the sodium nitrite quenching is not enough to create a fact question. He was correct and alerted numerous important department heads.[6] Moreover, ZHP's fatally weak basis for disputing what the email said was its expert Dr. Fengtian Xue's now excluded "reading."[7] (ECF 2581, at 18-19).

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[6] It is worth noting that the email was produced under suspicious circumstances (a pdf, and no other recipients were listed as custodians as required by the ESI protocol).

[7] The ZHP Defendants' opposition to Plaintiffs' statement of material facts also relies on the sanctions deposition of Jucai Ge, where she relied on her purported ex parte discussion with Jinsheng Lin to reinterpret the email as "poorly written and complicated … even though that was the words that said so on this page," meaning Plaintiffs' understanding of what the email actually states is accurate. (Jucai Ge 5/26/2022 Dep. Tr. 83:7-84:7 (ZHP Ex. 37); *see also id.* at 79:7-16). Jucai Ge's attempt to obfuscate the meaning of the email is based on impermissible hearsay and cannot be considered in opposition to Plaintiffs' motion for summary judgment or at trial. *See Chevron TCI, Inc. v. Capitol House Hotel Manager, LLC*, 541 F. Supp. 3d 687, 694 (M.D. La. 2021) (holding that "a corporate representative may not testify

The ZHP Defendants cite *Tershakovec v. Ford Motor Co.*, 546 F. Supp. 3d 1348, 1364-65 (S.D. Fla. 2021), for the idea that "one internal email" is not enough to prove ZHP's knowledge. (ZHP Opp. Br. 3-4). However, the *Tershakovec* case concerned whether a single customer complaint put the defendant on notice of a potential defect. 546 F. Supp. 3d at1364-65. Here, we have an internal smoking gun email written by a trusted scientist confirming knowledge of the **existence and root cause for the creation of the genotoxic probable human carcinogen at issue within the ICH cohort of concern, contaminating the drug in question that the company was actively selling as within all quality and purity specifications**. (Pls.' Affirmative SOMF ¶ 35-163.2). The two run-of-the-mill cases cited in Defendants' briefs are completely inapposite. (ZHP Opp. Br. 2). The Court should therefore reject Defendants' baseless attempt to conjure a factual dispute concerning the July 27, 2017 email that has been confirmed by ZHP via its corporate representative's admissions and ZHP's own English translation of the document.

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to matters outside his own personal knowledge 'to the extent that information [is] hearsay not falling within one of the authorized exceptions.") (quoting *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 435 (5th Cir. 2006)) (citing *Deutsche Shell Tanker Gesellschaft mbH v. Placid Refining Co.*, 993 F.2d 466, 473 (5th Cir. 1993)); *Diamond Offshore Co. v. Survival Sys. Int'l, Inc.*, 902 F. Supp. 2d 912, 932 (S.D. Tex. 2012) (holding: "The statements made on information and belief based on Mark Beatty's conversations with Captain Beatty are hearsay and cannot be transformed into admissible evidence simply because Mark Beatty is a corporate representative.").

VIII. COMMON LAW FRAUD CLAIMS AGAINST TORRENT.

Plaintiffs only seek summary judgment on the common law fraud claim against the Torrent entities for the very specific time frame of August 3, 2018, until August 17, 2018. While Plaintiff is not precluded from arguing common law fraud occurred before August 3, 2018, that time frame is not the subject of this Motion.

Torrent's primary argument is that Torrent did not have knowledge of the falsity of its misrepresentations. To this end, Defendants cite *Harris v. Pfizer Inc.* However, in *Harris*, Pfizer, a manufacturer of varenicline API, was notified that other products contained nitrosamines in 2018 and that their supply of varenicline *was at risk of* contamination in late 2020. Therefore, the Plaintiffs were unable to support a "strong inference" that Pfizer knew or believed nitrosamines were present in its API. *Harris*, at 241. In contrast, Torrent was specifically informed that *NDMA was actually present* in the API used in their VCDs on August 3, 2018; that is actual knowledge (; Torrent SOMF ¶ 15; Nigh Suppl. Cert. Ex. 29, Ex. 1, at 121:23–123:22, 138:5–8) Torrent did not disclose its knowledge until after August 17, 2018.

Each Torrent prescription reimbursed by TPPs between August 3-17, 2018 was premised on affirmative misrepresentations by Torrent that their VCDs were "valsartan" as FDA-approved, were manufactured in compliance with CGMPs, were therapeutic equivalents interchangeable with the RLDs Diovan and/or Exforge, and met compendial standards. This also constitutes common law fraud based on

Torrent's material omissions. When Torrent informed customers that its product was not involved in the recall in which valsartan products were being removed from the market due to the presence of nitrosamines, all the while being aware that a recall related to the very issue customers were concerned about was imminent, this was a "partial, ambiguous statement" that "required additional disclosure to avoid misleading" the purchasers of valsartan. *See Remington Rand Corp. v Amsterdam-Rotterdam Bank*, 68 F.3d 1478, 1484 (2d Cir 1995). Without explaining that NDMA had been, in fact, detected in its product, Torrent withheld and omitted critical facts that should have been shared with purchasers. Plaintiffs' motion should be granted.

IX. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT ON THE CPL SUBCLASS A CLAIMS.

Defendants' opposition on Plaintiffs' CPL Sublcass A claims rests on the same specious arguments that underpin the remainder of their defenses in this litigation (*i.e.,* Defendants' arguments that they did not violate CGMP, that their NDMA/NDEA-contaminated VCDs remained as approved "valsartan" and met compendial standards, and that their VCDs were not contaminated with "genotoxic" or "carcinogenic" impurities). (Defs.' Br. 17-32.)

First, Defendants argue—despite the Court's previous findings—that Pennsylvania and North Carolina do in fact require intent. This is not the case.[8] All

[8] North Carolina's highest court has unambiguously ruled as much. *Myers v. Liberty Lincoln-Mercury, Inc*., 365 S.E.2d 663, 664 (N.C. 1988) ("to prevail in a Chapter 75

that is required is that the conduct meet the CPL Subclass A states' definition of deception or unfairness.

As Plaintiffs explained in their Motion, what constitutes deception or unfairness under the CPL Subclass A states' laws is defined nearly identically with incorporation of FTC Act interpretations that unambiguously and undisputedly apply here. (Pls.' Br. 26-38.) Defendants incorrectly argue that is not the case, but that is exactly what they argue in footnote 12 of their brief.[9] Defendants specifically call out Connecticut as an example, but the selectively-quoted section of the pattern jury instructions (which are discretionary)[10] actually relates to materiality. *See* Conn.

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case, a purchaser of misrepresented merchandise does not have to prove fraud, bad faith or intentional deception as at common law; it is enough that the goods bought were misrepresented"). Nor is any showing of intent required as per the Pennsylvania Supreme Court's interpretation of Pennsylvania's CPL. *Gregg v. Ameriprise Financial, Inc.*, 245 A.3d 637, 647-48 (Pa. 2021).

[9] The point Defendants appear to be making is that these state courts may not be formally bound to FTC Act decisional law or guidance. However, Defendants put forth no case or theory that any state would depart from FTC Act guidance on this fact pattern. As set forth in the Motion, the conduct here involving the "sales of hazardous or systematically defective products [] without adequate disclosures" and "failure to meet warranty obligations" constitute quintessential deceptive conduct. (Pls.' Br. 28 (citing and quoting FTC Policy Statement on Deception)). The same is true for unfairness. There is no conceivable argument that Defendants' sale of VCDs laced with carcinogens did not cause substantial injury (economic and otherwise), nor is there any non-frivolous argument that there is some countervailing benefit to Defendants' sale of these contaminated prescription pharmaceuticals, and finally Defendants are estopped from claiming consumers/TPPs could have avoided the injury (since they themselves claim they could not have avoided the contamination). (Pls.' Br. 31-36 (citing and discussing FTC Policy Statement on Unfairness)).

[10] As in all or nearly all states, "the use of these [Connecticut] instructions is entirely discretionary" and they are not "guarantee[d]" as to their "legal sufficiency."

Gen. Stat. Ann. § 42-110b(b) (instructing courts to "be guided by interpretations given by the [FTC]"); *see also Mendelsohn v. BidCactus, LLC*, No. 3:11cv1500, 2012 WL 1058702, at *7 (D. Conn. March 28, 2012) ("capacity to deceive" standard based on FTC Act guidance). New Hampshire also uses a "capacity to deceive" standard as set forth in Defendants' Opposition because New Hampshire also incorporates FTC Act standards. N.H. Rev. Stat.Ann. § 358- A:13.

Defendants suggest that Plaintiffs have not articulated a standard under Missouri, Nebraska, Oklahoma, Oregon, or Pennsylvania law. (Defs.' Br. 36). But Plaintiffs' Motion cites law for each of these jurisdictions as to their liberal and equitable constructions of these phrases. (Pls.' Br. 34-36). Some of the more specific provisions of these statutes likewise fit the undisputed factual record here, including representing goods to be of particular quality if they are not or representing that goods have approvals they do not. *See, e.g.*, Pa. Stat. 201-2(4)(ii), (iii), (v), (vii).

For unfairness, Defendants assert that Connecticut, Florida, Hawaii, Illinois,[11] Missouri, and Oklahoma's standard is "materially different" from the FTC test, but cite literally zero authority in support of that contention. Florida follows the FTC guidance. *Hill Dermaceuticals, Inc. v. Anthem, Inc.*, 228 F. Supp. 3d 1292, 1302

(Preface to Connecticut Pattern Jury Instructions).

[11] Although Plaintiffs had originally moved for certification with Illinois in this CPL Subclass A, the outcome of the class certification decision and notice programs shifted Illinois to CPL Subclass D. (*See* ECF 2532-6 & 2535). Accordingly, Plaintiffs do not understand Illinois CPL claims to be part of the upcoming trial.

(M.D. Fla. 2017). The remainder of these jurisdictions have adopted the FTC's less onerous cigarette rule test (Connecticut, Hawaii Missouri, Oklahoma), which is not inconsistent with the FTC's test described at Plaintiffs' Brief at 31-36 (and on which a jury can be instructed). Defendants refer to it as a "three-factor test," but it is actually disjunctive, and one of the ways to meet the standard is to establish that the conduct "[o]ffends any public policy as it has been established … by the Federal Trade Commission, or its interpretive decisions." *Ward v. W. Cnty. Motor Co.*, 403 S.W.3d 82, 84 (Mo. 2013), *as modified* (May 28, 2013).[12]

Finally, California employs a "likely to be deceived" standard for deception and also adopted the FTC definition of unfairness. *Kasky v. Nike, Inc*., 27 Cal.4th 939, 951 (2002); *Camacho v. Automobile Club of Southern California*, 142 Cal. App. 4th 1394, 1403 (2006). In any case, the California UCL § 17200 claim is to be tried to the Court directly (absent a summary judgment ruling), as there is no right to a jury trial for this claim. *Nationwide Biweekly Administration Inc. v. Superior*

[12] *A-G Foods, Inc. v. Pepperidge Farm, Inc.*, 216 Conn. 200, 215 (Conn. 1990) (practice is "unfair" if it offends an "established concept of unfairness"); Okla. Stat. tit. 15 § 752(14) (broadly defining "unfair" practice as a practice which "offends established public policy"). Defendants assert Nebraska and New Hampshire have their own distinct tests. Not true for Nebraska. *Raad v. Wal-Mart Stores, Inc*., 13 F. Supp. 2d 1003, 1018 (D. Neb. 1998) (a practice is "unfair" if it offends an "established concept of unfairness"). For New Hamphshire, although the "rascality" test is one formulation, that is not some magic phrase. *Ne. LumberMfrs. Assoc. v. N. StatesPallet Co*., 710 F. Supp. 2d 179, 188 (D.N.H. 2010); *see also Becksted v. Nadeau*, 926 A.2d 819, 822-23 (N.H. 2007) (in addition to rascality test, noting that N.H. also "look for guidance to the federal courts' interpretation of the [FTCA]").

Court of Alameda County, 462 P.3d 461, 473 (Cal. 2020).

Defendants also contort the undisputed facts. In addition to the points above (which apply equally to Plaintiffs' CPL claims), Defendants incredibly argue that there were "no regulations or limits applicable to NDMA or NDEA content during the relevant time period." (Defs.' Br. 38-39) The opposite is in fact true. The 2008 FDA Guidance titled "Prevention of Genotoxic and Carcinogenic Impurity Formation," cited in ZHP's DMFs for both processes, provided that "every feasible technical effort should be made to prevent the formation of genotoxic or carcinogenic compounds during drug substance synthesis or drug product manufacturing." (Pls.' Affirm. ZHP SOMF ¶ 57-58, 130-131). And NDMA and NDEA are part of the cohort of concern of "high potency mutagenic carcinogens" pursuant to ICH M; thus, the applicable limit during the relevant time period was zero. (*Id.* at ¶ 87).

Defendants also perversely rely on the fact that patients were advised not to discontinue taking the contaminated valsartan until first and promptly consulting their doctor. The balance was potential immediate death from heart attack or stroke versus further exposure to a carcinogen. This advice in no way provides a defense.

Defendants also continue to describe the VCDs contamination as "trace" and then make the illogical leap to argue that their drugs were not contaminated with carcinogenic impurities. (Defs.' Br. 29-30). These characterizations are simply false.

The undisputed factual record shows, based on testing conducted by Defendants themselves, that even by their own terms, Defendants' VCDs contained unacceptable levels of NDMA and NDEA, up to *hundreds* of times the eventual acceptable intake limit set by the FDA. (*See, e.g.,* Pls' ZHP SOMF ¶ 31 (ZHP product testing at levels up to 627 times the eventual NDMA limit)).

Finally, Defendants argue that there is a genuine issue of material fact as to whether the conduct was unfair, arguing that their sale of adulterated and carcinogen-laced VCDs did not cause any substantial injury and that the harm was outweighed by countervailing benefits. Aside from patients' ingestion of extraordinarily high amounts of potent carcinogens, the amount of economic damages being sought alone undercuts that specious argument. In addition, Defendants continue to simply pretend that the choice for patients was contaminated VCDs or none at all, which rests on false facts. At all times, non-adulterated non-contaminated VCDs and other therapies were available. Defendants' conduct offered no benefit.

Finally, Defendants take issue with whether the injury could have been avoided. TPPs did not need to do any formulary management since the VCDs were recalled and Defendants were not allowed to continue selling them without changing their processes. Moreover, TPPs routinely do and did flag the relevant NDCs for non-reimbursement. (Pls. Opp. to Defs' SOMF ¶ 108, 124).

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motions for partial summary judgment.

Dated: January 31, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2024, I electronically filed this partially redacted brief with the Clerk of the Court using CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL. In addition, I hereby certify that an unredacted copy of my supporting certification will be served contemporaneous to filing via email on the Court, Special Master, and Jessica Davidson at Jessica.Davidson@skadden.com, Lori Cohen at CohenL@gtlaw.com, and Jay Lefkowitz at lefkowitz@kirkland.com.

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Dated: January 31, 2024